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SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.

EXAMINER	
ART UNIT	PAPER NUMBER
	6

DATE MAILED:

02/25/82

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

- ☐ This application has been examined. ☒ Responsive to communication filed on 12/4/82 ☒ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), — days from the date of this letter.  
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892 2. ☐ Notice of Informal Patent Drawing, PTO-948  
3. ☐ Notice of References Cited by Applicant, PTO-1449 4. ☐ Notice of Informal Patent Application, Form PTO-152

Part II SUMMARY OF ACTION

5. ☐ \_\_\_\_\_
1. ☒ Claims 1-19 are pending in the application.  
Of the above, claims \_\_\_\_\_ are withdrawn from consideration.
2. ☐ Claims \_\_\_\_\_ have been cancelled.
3. ☐ Claims \_\_\_\_\_ are allowed.
4. ☒ Claims 1-19 are rejected.
5. ☐ Claims \_\_\_\_\_ are objected to.
6. ☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.
7. ☐ The formal drawings filed on \_\_\_\_\_ are acceptable.
8. ☐ The drawing correction request filed on \_\_\_\_\_ has been ☐ approved. ☐ disapproved.
9. ☐ Acknowledgment is made of the claim for priority under 35 U.S.C. 119. The certified copy has  
☐ been received. ☐ not been received. ☐ been filed in parent application, serial no. \_\_\_\_\_,  
filed on \_\_\_\_\_.
10. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
11. ☐ Other

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The references presented by applicants should be cited on a notice of references cited by applicant, PT -1449 form.

35 U.S.C. 101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

Claims 1-19 are rejected under 35 U.S.C. 101 because there is insufficient evidence of record demonstrating the applicants' compound is effective for treating cancer in humans. The case histories in the references are incomplete as to form and substance in the omission of a protocol and complete pertinent data for evaluation of the results by one skilled in the art. The data of record is obviously no substitute for a showing of such utility in humans by proper evidence with statistically significant data, based on all tests unducted. In re Buting 163 U.S.P.Q. 689

Claims 1-19 are rejected as being based on an insufficient disclosure under 35 USC 112, first paragraph. The term "neoplastic disease" in claim 1 and 2; "pulmonary metastatic tumor" in claim 3;

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"breast cancer" in claim 4 and 5; "lung cancer" in claims 6 and 7; "malignant melanoma" in claim 8 and 9; "colorectal cancer" in claim 10 and 11; "multiple myeloma" in claims 12 and 13; "head and neck cancer" in claim 14 and 15; "bladder cancer" in claims 16 and 17 and "gastric cancer" in claims 18 and 19 lack clear exemplary support in the specification as filed. The limited number of examples set forth in the specification will obviously not support such broad terms.

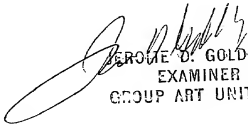
THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). The practice of automatically extending the shortened statutory period an additional month upon the filing of a timely response to a final rejection has been discontinued by the Office. See 1021 TMOG 35.

JDGoldberg:adj

A/C 703

557-2575

02/15/83

  
JEROME D. GOLDBERG  
EXAMINER  
GROUP ART UNIT 125